K141306

Appendix E

JUN 12 2014

510(k) Summary in accordance with 21 CFR 807.92(c)

Device Name:	Teva Medical I.V. Administration Set
Type of 510(k) submission:	Special
Date of Submission:	16 May 2014
Manufacturer:	Teva Medical Ltd., MIGADA Plant North Industrial Zone Kiryat Shmona 10258 ISRAEL
FDA Registration Number:	9611423
Owner/Operator Number:	9001925
510(k) Owner:	Teva Medical Ltd., MIGADA Plant North Industrial Zone Kiryat Shmona 10258 ISRAEL
Phone: **Fax:**	+972 (0)46 908822 +972 (0)39 267865
510(k) Submitter and Contact:	Mr Roger Gray VP Quality and Regulatory Donawa Lifescience Consulting Piazza Albania 10 00153 Rome Italy Phone: +39 06 578 2665 Fax: +30 06 574 3786 Email: rgray@donawa.com
FDA Product Code:	FPA
FDA Regulation Number:	880.5440
FDA Classification Name:	Set, Administration, Intravascular
Classification Panel:	General Hospital
Common Name:	I.V. Administration Set
FDA Classification:	Class II
FDA Identification:	An intravascular administration set is a device used to administer fluids from a container to a patient's vascular system through a needle or catheter inserted into a vein. The device

may include the needle or catheter, tubing, a flow regulator, a drip chamber, an infusion line filter, an I.V. set stopcock, fluid delivery tubing, connectors between parts of the set, a side tube with a cap to serve as an injection site, and a hollow spike to penetrate and connect the tubing to an I.V. bag or other infusion fluid container.

Indications for Use: The I.V. Administration Set is a single use, sterile I.V. set for administration of drugs and/ or fluids from a container to a patient vascular system.

Device Description:

The I.V. Administration Set is single use, sterile, non-pyrogenic device used to administer intravenous solutions and/or drugs solutions from a container to a patient's vascular system.

The I.V Administration set is comprised of various generic components which are broadly used through the industry such as: Spike, Y-site, tubing, clamp, needless injection site, 'twist-off' and Luer connection.

The purpose of this Special 510(k) is to add the following two new designs of IV Administration Sets to the one already cleared for sale in the US under K121269:

- TEVADAPTOR Connecting Set with ULTRASITE Injection Site
- TEVADAPTOR Spike Port Adaptor with ULTRASITE Injection Site

All components used in the two new Administration Sets were used in the predicate device cleared under K121269, except for two, which are identical to components cleared under K071741.

Because none of the materials are new, and all components have been previously cleared for use in IV administration sets, no additional biocompatibility data is included in this submission.

Comparison with predicate device:

The predicate device selected for comparison with the I.V. Administration Set is:

Predicate Device: ..... I.V. Administration Set
510(k) Sponsor: ..... Teva Medical
510(k) Number: K121269
Clearance Date: ..... 22 January 2013
FDA Product Code: ..... FPA
Classification Name: ..... Set, Administration, Intravascular
Regulation No: 880.5440

The following aspects of the subject and predicate devices are identical:

- Indications for use
- Fundamental technology
- Single use only
- Sterilization
- Biocompatibility
- Interconnecting features

- Interaction with patient and other devices
- Safety features

The following aspects of the devices are different:

- The lengths of the new devices are shorter than the predicate.
- No drip chamber, flow control or air venting in the new devices.
- Addition of the twist-off component in one of the new devices.
- Labeling has changed as a result of the above differences.
- Packaging materials and process has changed

The two additional (subject) devices have been reviewed under the control of Teva Medical's quality management system and none of the changes from the predicate device have been identified as having any significant effect on safety and effectiveness compared with the original FDA-cleared device. Where verification/validation of applicable changes was required, these have been carried out under the control of Teva Medical's quality system, which is in compliance with 21 CFR 820.

Substantial Equivalence Conclusion:

Based on the information contained within this submission, the additional subject device administration sets do not raise any additional safety and effectiveness issues. It is concluded that the additional devices are substantially equivalent to the identified predicate device cleared under K121269, which is already in interstate commerce within the USA.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

June 12, 2014

Teva Medical Limited, MIGADA Plant
C/O Mr. Roger Gray
Donawa Lifescience Consulting
Piazza Albania 10
00153 Rome
Italy

Re: K141306
Trade/Device Name: Teva Medical I.V. Administration Set
Regulation Number: 21 CFR 880.5440
Regulation Name: Set, Administration, Intravascular
Regulatory Class: II
Product Code: FPA
Dated: May 16, 2014
Received: May 19, 2014

Dear Mr. Gray:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mary S. Runner -S

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K141306

Device Name
Teva Medical I.V. Administration Set

Indications for Use *(Describe)*
The I.V. Administration Set is a single use, sterile I.V. set for administration of drugs and/or fluids from a container to a patient vascular system.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Digitally signed by
Richard C. Chapman -S
Date: 2014.06.12
13:24:34 -04'00'

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